Insulet Corporation
Julie Perkins
Sr. Director, Regulatory Affairs/Quality Assurance
100 Nagog Park
Acton, Massachusetts 01720

Re: K192659
Trade/Device Name: Omnipod Insulin Management System, Omnipod DASH Insulin Management System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG, NBW, NDC
Dated: September 24, 2019
Received: September 25, 2019

Dear Julie Perkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For CDR Nikhil Thakur
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192659

Device Name

Omnipod DASH Insulin Management System

Indications for Use *(Describe)*

The Omnipod DASH Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.

Additionally, the Omnipod DASH System is interoperable with a compatible blood glucose meter to receive and display glucose measurements.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192659

Device Name
Omnipod Insulin Management System

Indications for Use *(Describe)*

The Omnipod Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro) from the finger.

The glucose measurements should not be used for the diagnosis of or screening for diabetes. The PDM glucose meter is intended for single-patient use and should not be shared.

Abbott FreeStyle test strips are used with the built-in FreeStyle meter for the quantitative measurement of blood glucose in fresh whole capillary blood from the finger, upper arm and palm. Abbott Freestyle Control Solutions are used to verify that the meter and test strips are working together properly and that the test is performed correctly.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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omnipod®
INSULIN MANAGEMENT SYSTEM

K192659 510(k) Summary

Date prepared:	October 21, 2019
Submitter Name:	Insulet Corporation
Submitter Address:	100 Nagog Park Acton, MA 01720
FDA Establishment Owner/Operator Number:	9056196
FDA Establishment Registration Number:	3014585508
Contact Person:	Julie Perkins Sr. Director of Regulatory Affairs and Quality Assurance
Phone:	(978) 600-7951(office)
Fax:	(978) 600-0120
Device Trade / Proprietary Name:	Omnipod® Insulin Management System Omnipod DASH™ Insulin Management System
Device Common Name:	Pump, Infusion, Insulin
Regulation Description:	Infusion pump
Regulation Medical Specialty:	General Hospital
Review Panel:	General Hospital
Product Code:	LZG (Infusion Pump) NBW (System, Test, Blood Glucose, Over the Counter) NDC (Calculator, Drug Dose)
Submission Type:	Traditional 510(k)
Regulation Number:	880.5725
Device Class:	Class II
Device predicate:	K182630 Omnipod® Insulin Management System, Omnipod DASH™ Insulin Management System

omnipod®
INSULIN MANAGEMENT SYSTEM

Purpose of Submission:

Modification to K182630 Omnipod and Omnipod DASH Insulin Management Systems to address labeling change for compatible insulins.

Device Description:

The subject devices provide for the management of insulin therapy by patients with diabetes mellitus. The devices are comprised of two primary components: the disposable insulin infusion pump (Pod) and an associated wireless remote controller referred to as the Personal Diabetes Manager (PDM). The PDMs incorporates a suggested bolus calculator which aids the user in determining the insulin bolus dosage needed based on carbohydrates ingested, most recent blood glucose reading, programmable correction factor, insulin to carbohydrate ratio, target blood glucose value, and Insulin on Board (IoB).

The Pod is a body-wearable insulin pump that affixes to the user on the back of the arm, the lower back or abdomen, the thigh area, or any site that has a layer of fatty tissue available. It is held in place by an adhesive pad and provides up to three days of insulin before it is removed and replaced with a new Pod. The PDM is a handheld device that controls the Pod. The user interfaces with the device system through the PDM, where they control basal and bolus delivery and various insulin program settings and calculations. The PDM also has a food library to assist with carbohydrate calculations, and it maintains several variables in a history log for the viewer to track their diabetes therapy. The Omnipod Insulin Management System PDM has an integrated blood glucose meter and communicates with the Pod using wirelessly using secure, low power, bi-directional radio frequency (RF) communications at 433.92MHz. The Omnipod DASH Insulin Management System PDM does not have an integrated blood glucose meter, but is interoperable with a compatible blood glucose meter to receive and display glucose measurements. The Omnipod DASH PDM communicates to the Pod and a compatible blood glucose meter using Bluetooth Low Energy.

The systems are for prescription use only.

Indications for Use:

Omnipod Insulin Management System

The Omnipod® Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro) from the finger.

The glucose measurements should not be used for the diagnosis or screening for diabetes. The PDM glucose meter is intended for single patient use and should not be shared.

Abbott FreeStyle® test strips are used with the built-in FreeStyle meter for the quantitative measurement of blood glucose in fresh whole capillary blood from the finger, upper arm and palm. Abbott Freestyle Control Solutions are used to verify that the meter and test strips are working together properly and that the test is performed correctly.

Omnipod DASH Insulin Management System
The Omnipod DASH™ Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.

Additionally, the Omnipod DASH System is interoperable with a compatible blood glucose meter to receive and display glucose measurements.

Substantial Equivalence Discussion

Intended Use Comparison
The table below includes a comparison of the intended use between the new device and those of the predicate device:

Characteristic	**Predicate Device** Device Name K182630	**Subject Device** Device Name K192659
Indications for Use	Omnipod Insulin Management System The Omnipod® Insulin Management System is intended for subcutaneous	Omnipod Insulin Management System The Omnipod® Insulin Management System is intended for subcutaneous

	delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro) from the finger. The glucose measurements should not be used for the diagnosis or screening for diabetes. The PDM glucose meter is intended for single patient use and should not be shared. Abbott FreeStyle® test strips are used with the built-in FreeStyle meter for the quantitative measurement of blood glucose in fresh whole capillary blood from the finger, upper arm and palm. Abbott Freestyle Control Solutions are used to verify that the meter and test strips are working together properly and that the test is performed correctly. <u>Omnipod DASH Insulin Management System</u> The Omnipod DASH Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes	delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro) from the finger. The glucose measurements should not be used for the diagnosis or screening for diabetes. The PDM glucose meter is intended for single patient use and should not be shared. Abbott FreeStyle® test strips are used with the built-in FreeStyle meter for the quantitative measurement of blood glucose in fresh whole capillary blood from the finger, upper arm and palm. Abbott Freestyle Control Solutions are used to verify that the meter and test strips are working together properly and that the test is performed correctly. <u>Omnipod DASH Insulin Management System</u> The Omnipod DASH™ Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes

	mellitus in persons requiring insulin. Additionally, the Omnipod DASH System is interoperable with a compatible blood glucose meter to receive and display glucose measurements.	mellitus in persons requiring insulin. Additionally, the Omnipod DASH System is interoperable with a compatible blood glucose meter to receive and display glucose measurements.
Prescription Only or Over the Counter	Prescription Only	Prescription Only
Intended Population	General Use	General Use
Environment of Use	Home Use	Home Use

Discussions of differences in Indications for Use statement
The indications for use statement for the subject device is identical to the predicate device.

Discussions of differences in intended population
The intended population for the subject device is identical to the predicate device.

Discussions of differences in environment of use
The environment of use for the subject device is identical to the predicate device.

Summary of Technological Characteristics Compared to Predicate Devices:

The subject devices are identical to the predicate devices. The technological characteristics, design, energy source, principals of operation, and configuration of the Omnipod® and Omnipod DASH™ Insulin Management Systems have not changed from the devices cleared in K182630. The modification being proposed is to the labeling only to add Fiasp U100 as an insulin that has been tested for use with the Omnipod and Omnipod DASH Systems.

There have been no changes to the device materials, software, sterilization method, or packaging of the systems that is subject of this 510(k).

Performance Data and Standards Compliance:

The following performance testing data were provided in support of the substantial equivalence determination.

- **Drug Stability and Compatibility;** In-use stability and leachables testing was conducted with Fiasp U100 insulin to verify and validate that the systems do not adversely affect the insulin.
- **Safety Assurance Case;** An assurance case for each system was provided as recommended in the FDA Guidance: Infusion Pumps Total Product Life Cycle.

  The stated goal of the Omnipod Insulin Management System safety assurance case is:

  > The Omnipod® Insulin Management System with blood glucose monitor and dose calculator is acceptably safe for the infusion of U100 insulin that is approved for use in pumps, for use in the home setting by people with diabetes mellitus who require insulin on a daily basis.

  The stated goal of the Omnipod DASH Insulin Management System safety assurance case is:

  > The Omnipod DASH™ Insulin Management System with dose calculator is acceptably safe for the infusion of U100 insulin that is approved for use in pumps, for use in the home setting by people with diabetes mellitus who require insulin on a daily basis.

  Additions to the safety assurance case from the predicate devices' cases include use of the device with Fiasp U100.

  The following specific evidence was included within the assurance case to demonstrate that the subject device is verified and validated for its intended use and to demonstrate substantial equivalence to the predicate devices:

  - Fiasp stability testing in Omnipod Pods
  - Leachables study

- **Risk Management;** was completed in accordance with ISO 14971:2007- Medical Devices- Application of Risk Management to Medical Devices.

Verification activities, as required by the risk analysis, demonstrated that the predetermined acceptance criteria were met and the devices are safe for use.

The Omnipod and Omnipod DASH Insulin Management Systems comply with the following standards as documented in the predicate devices (K182630) and in the applicable test reports provided in this 510(k) submission.

- ISO 10993-1 (2009)- 4th Edition Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing within a Risk Management Process
- ISO 14971 Second Edition 2007-03-01 Medical Devices- Application of Risk Management to Medical Devices

Substantial Equivalence Conclusion:

The subject Omnipod® and Omnipod DASH™ Insulin Management Systems use the same technology, modes of operation, and indications for use as the devices cleared in K182630. The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The subject devices are substantially equivalent to the predicate devices with respect to the indications for use, target populations, treatment method, and technological characteristics.